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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/047,461	01/14/2002	Andras Guttman	1360.034US1	3157

25297 7590 09/27/2005

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EXAMINER

BARTON, JEFFREY THOMAS

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 09/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/047,461

Applicant(s)

GUTTMAN ET AL.

Examiner

Jeffrey T. Barton

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 16 and 49-63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 15, 16 and 49-63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 20050523.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed on 20 July 2005 does not place the application in condition for allowance.

***Status of Rejections Pending Since the Office Action of 18 February 2005***

2. The rejections of claims 13 and 14 are obviated due to cancellation of the claims.
3. The rejection of claims 1-12, 15, 16, and 49-53 as unpatentable over Finney et al in view of Rice et al is withdrawn due to Applicant's amendment.
4. The rejection of claims 54-61 as unpatentable over Finney et al in view of Rice et al and Johansson et al is withdrawn due to Applicant's amendment.

***Claim Rejections - 35 USC § 103***

5. Claims 1-12, 15, 16, 49-53, 62, and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finney et al in view of Rice et al and Zhang et al.

Regarding claims 1, 49, 62, and 63, Finney et al disclose an electrophoresis system comprising two buffer reservoirs with electrode terminals (Figure 1, reservoirs 40 and 50 with terminals visible on their near ends); and a chamber coupled to the reservoirs (defined by spacer 20) having a bottom plate (30) and top plate (11) in parallel alignment and holding separation medium therein. (Column 15, lines 2-8)

Regarding claims 2-6, Finney et al disclose using glass top and bottom plates, with variable thickness, separated from each other by as little as 100 microns. (Column 10, lines 31-40; Column 14, lines 40-55; Column 15, lines 6-14)

Regarding claim 7, the buffer reservoir bodies (40 and 50) can be called "covers", as they cover portions of the top and bottom plates 11 and 30.

Regarding claim 13, Finney et al disclose a band detector. (Column 17, lines 1-10)

Regarding claims 15 and 16, Finney et al disclose the terminals being connected to poles of a power supply. (Column 11, lines 7-19)

Relevant to claim 53, Finney et al disclose the separation medium being a gel.  
(Title)

Specific to the combination with Rice et al, Finney et al disclose forming sample wells using a comb that provides regularly-spaced wells in the gel. (Figure 3) The comb is applied via apertures in the bottom of the cathode buffer reservoir. (Column 12, lines 30-53) Samples are disclosed as being manually or automatically applied to the gel via these wells.

Specific to the combination with Zhang et al, Finney et al suggest using known methods of detection for analyzing the gels. (Column 17, lines 1-11)

Finney et al do not explicitly disclose a system comprising a sample delivery device having a longitudinal axis and having a plurality of tabs extending orthogonally from this axis, the device being adapted to couple with an opening of a reservoir of the

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device. They also do not explicitly disclose providing an optical densitometer functionally coupled to the chamber.

Rice et al disclose a membrane loader for use in applying samples to electrophoresis gels (e.g. Figure 6a), which has a longitudinal axis with a plurality of tabs extending orthogonally from this axis, the loader adapted to couple to an opening corresponding to a sample loading position within an electrophoresis cassette. (e.g. Figure 1a)

Relevant to claims 8-10 and 50-52, the membrane loader includes a nanoporous membrane: (Examples given in the Table of Columns 13-16 - pores as small as 50 nm in No. 33)

Relevant to claims 11 and 12, Rice et al disclose more than five tabs. (Figure 6a) They also disclose 2.5 mm wide tabs with 1 mm spacing between them (Column 13, lines 1-7). (i.e. 3.5 mm/tab over the length of the loader)

Relevant to claims 62 and 63, Rice et al disclose an embodiment of their membrane loader (e.g. Figures 6a and 6b) wherein the membrane is disposed on a substrate that reinforces, partially overlaps, and is bonded to the membrane loader. (Column 9, lines 18-64 - a substrate that "structurally supports" reads on the instantly claimed "reinforcer", and since the membrane is formed by dipping the substrate in a membrane slurry material that coats the substrate, the membrane can be said to "overlap" the reinforcer in a "lamine region")

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the system of Finney et al by using the membrane loader of Rice et al to load samples into the gel, because Rice et al teach that it simplifies sample loading onto gels by reducing the dexterity required and that it also reduces loading time, among other benefits. (Column 6, line 60 - Column 7, line 1; also the Background section details drawbacks of the prior methods)

In such a combination, it could accurately be said that the sample delivery device (membrane loader) is coupled with openings of the cathode reservoir, as the tabs would be inserted through the same apertures within the reservoir base that held the comb in the gel molding step. (Column 12, lines 30-53; Figure 3)

Further addressing claim 5, choice of any specific plate spacing would be within the abilities of one having ordinary skill in the art, depending on the specific experiment to be run.

Further addressing claim 12, given the disclosed width of the gels of Finney et al (20-30 cm; Column 10, lines 31-37) and the tab spacing disclosed by Rice et al (3.5 mm/tab), there would be about 57-86 tabs on this loader.

Zhang et al disclose a slab gel electrophoresis system, in which they use an optical densitometer to produce an image of the stained gel. (Column 11, lines 6-11)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the system of Finney et al by using a optical densitometer for spot detection, as taught by Zhang et al, because Finney et al disclose

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that their system can be used with known prior art detection methods (Column 17, lines 1-11) and Zhang et al teach the usefulness of optical densitometry in producing an electronic image of the gel for storage and later analysis. Regarding the limitation that the densitometer be “functionally coupled” to the chamber, the breadth of this term falls within the disclosure of the cited references. The function of the chamber of Finney et al is to contain the gel during electrophoresis and the function of the densitometer of Zhang et al is to analyze the gel after the separation. These functions are certainly “coupled” to each other within the electrophoresis experiment, and therefore read on the claim.

6. Claims 54-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finney et al, Rice et al, and Zhang et al as applied to claim 49 above, and further in view of Johansson et al.

Finney et al, Rice et al, and Zhang et al disclose systems as described above. Finney et al disclose no particular gel to be used in their cassette, referring only to a generic gel material. (e.g. Column 4, line 56 - Column 5, line 7)

None among Finney et al, Rice et al, or Zhang et al explicitly disclose using media of the claimed compositions or media adapted for separation of molecules of these molecular weight ranges.

Johansson et al disclose using mixtures of agarose and linear polyacrylamide to separate plasma proteins. The agarose percentage falls in the specified range (Paragraph bridging pages 202 and 203), as does the acrylamide percentage. (Figure 2,

Page 206-207) The globulins separated also fall within the claimed molecular weight ranges. ( $\gamma$ - and  $\alpha_2$ - $\beta$ -globulin)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to further modify the system of Finney et al and Rice et al by using a mixed agarose/linear polyacrylamide matrix, as taught by Johansson et al, because Finney et al specifies no gel to be used with their system, suggesting that gels known in the prior art would be suitable. Furthermore, Johansson et al teach the advantages of the mixed agarose/LPA system in reducing the effects of electroosmosis, obtaining gels with some advantages of both polyacrylamide and agarose, and in some sharpening of protein bands, in comparison to untreated agarose. (Page 211, 2<sup>nd</sup> full paragraph - Page 212; Paragraph bridging pages 206 and 207)

Additionally, it would be within the abilities of one having ordinary skill in the art to select a suitable gel from among those known in the prior art for use within the system of Finney et al.

### ***Response to Arguments***

7. Applicant's arguments filed on 20 July 2005 have been fully considered but they are not persuasive.

Applicant argues that Zhang et al does not teach "functionally coupling" an optical densitometer to the chamber, and in fact teaches away from such coupling in that they remove the gel from the electrophoresis system prior to densitometry analysis.



(Paragraph bridging pages 16 and 17) The Examiner respectfully considers Applicant's reading of "functionally coupled" to be narrower than justified in the claim.

As stated in the rejection above, the function of the chamber of Finney et al is to contain the gel during electrophoresis and the function of the densitometer of Zhang et al is to analyze the gel after the separation. These functions are certainly "coupled" to each other within the electrophoresis experiment, and therefore read on the claim.

Indeed, any devices that perform a function within the process of the overall electrophoresis experiment (e.g. apparatus preparation, sample loading, electrophoretic separation, and gel analysis) can accurately be described as "functionally coupled".

Regarding new claims 62 and 63, Applicant contends that the substrate 502 shown in Figure 6b of Rice et al does not meet the limitations of these claims, as the membrane is attached to the bottom of the substrate with no overlap. (Page 21, 2<sup>nd</sup> full paragraph) As stated in the rejection above, Rice et al disclose forming of the membrane by dipping the substrate into a membrane slurry mixture, thereby coating a portion of the substrate. (Column 9, lines 36-40) This reads on the limitations to overlapping and bonding such that a laminate region is formed.

### ***Conclusion***

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Jeffrey Barton, whose telephone number is (571) 272-1307. The examiner can normally be reached Monday-Friday from 8:30 am – 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached at (571) 272-1342. The fax number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

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JTB

20 September 2005

A handwritten signature in black ink, appearing to read 'Alan Diamond', with a stylized flourish at the end.

**ALAN DIAMOND**  
**PRIMARY EXAMINER**

Tech Center 1700